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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAFEWAY INC.; WALGREEN CO.; THE
KROGER CO.; NEW ALBERTSON'S, INC.;
AMERICAN SALES COMPANY, INC.; and
HEB GROCERY COMPANY, LP,

Case No.: C 07-5470 CW

**AMENDED COMPLAINT
JURY TRIAL DEMANDED**

Plaintiffs,

v.

ABBOTT LABORATORIES,

Defendant.

NATURE OF THE ACTION

This a civil antitrust action challenging Abbott Laboratories' unlawful monopolization and attempted monopolization of the market for boosted protease inhibitors, a class of drugs used to treat medical disorders caused by the human immunodeficiency virus, or HIV. Abbott Laboratories ("Abbott") has unlawfully leveraged its monopoly position as the sole provider of Norvir, a protease inhibitor ("PI") that is used to boost the therapeutic effects of other protease inhibitors, in order to disadvantage its competitors and restrict competition in the closely related boosted PI market. This unlawful scheme has resulted in a suppression of

1 competition in the boosted PI market and has caused Plaintiffs and other purchasers to pay
2 supracompetitive prices for the relevant drugs.

3 **PARTIES**

4 1. Plaintiff Safeway Inc. ("Safeway") is a Delaware corporation having its
5 principal place of business in Pleasanton, California, which is located in the Oakland Division
6 of this Court. Safeway owns and operates retail stores in several states at which it dispenses
7 prescription drugs to the public, including Norvir and Kaletra. Safeway brings this action in its
8 own behalf and as the assignee of McKesson Corporation ("McKesson"), a pharmaceutical
9 wholesaler, which during the relevant period purchased those drugs directly from Abbott for
10 resale to Safeway and which has assigned its claims arising out of those purchases to Safeway.

11 2. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its
12 principal place of business in Deerfield, Illinois. Walgreen owns and operates retail stores in
13 several states at which it dispenses prescription drugs to the public, including Norvir and
14 Kaletra. Walgreen purchased Norvir and/or Kaletra directly from Abbott during the relevant
15 period. Walgreen brings this action in its own behalf and as the assignee of Cardinal Health,
16 Inc. ("Cardinal"), a pharmaceutical wholesaler, which during the relevant period purchased
17 those drugs directly from Abbott for resale to Walgreen and which has assigned its claims
18 arising out of those purchases to Walgreen.

19 3. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its
20 principal place of business in Cincinnati, Ohio. Kroger owns and operates retail stores in
21 several states at which it dispenses prescription drugs to the public, including Norvir and
22 Kaletra. Kroger purchased Norvir and/or Kaletra directly from Abbott during the relevant
23 period. Kroger brings this action in its own behalf and as the assignee of Cardinal, which
24 during the relevant period purchased those drugs directly from Abbott for resale to Kroger and
25 which has assigned its claims arising out of those purchases to Kroger.

26 4. Plaintiff New Albertson's, Inc. ("Albertson's") is a Delaware corporation
27 having its principal place of business in Boise, Idaho. Albertson's owns and operates retail
28 stores in several states at which it dispenses prescription drugs to the public, including Norvir

1 and Kaletra. Albertson's brings this action in its own behalf and as the assignee of McKesson,
2 which during the relevant period purchased those drugs directly from Abbott for resale to
3 Albertson's and which has assigned its claims arising out of those purchases to Albertson's.

4 5. Plaintiff American Stores Company, Inc. ("ASC") is a Delaware
5 corporation having its principal place of business in Lancaster, New York. ASC purchases
6 pharmaceutical and other products and distributes those products to retail stores owned and
7 operated by affiliated companies. ASC purchased Norvir and/or Kaletra directly from Abbott
8 during the relevant period. ASC brings this action in its own behalf and as the assignee of
9 Cardinal, which during the relevant period purchased Norvir and Kaletra directly from Abbott
10 for resale to ASC and which has assigned its claims arising out of those purchases to ASC.

11 6. Plaintiff HEB Grocery Company, LP ("HEB") is a Texas limited
12 partnership having its principal place of business in San Antonio, Texas. HEB owns and
13 operates retail stores in several states at which it dispenses prescription drugs to the public,
14 including Norvir and Kaletra. HEB brings this action in its own behalf and as the assignee of
15 Cardinal, which during the relevant period purchased Norvir and Kaletra directly from Abbott
16 for resale to HEB and which has assigned its claims arising out of those purchases to HEB.

17 7. Defendant Abbott is a corporation organized and existing under the laws
18 of the State of Illinois and having its principal place of business in Abbott Park, Illinois.
19 Abbott is engaged in the development, manufacture and sale of pharmaceutical and nutritional
20 products. Abbott has facilities in 14 states, including several in this District.

21 **JURISDICTION AND VENUE**

22 8. This action arises under section 2 of the Sherman Act, 15 U.S.C. § 2, and
23 sections 4 and 16 of the Clayton Act, 15 U.S.C. §§15(a) and 26. The Court has subject-matter
24 jurisdiction pursuant to 28 U.S.C. §§1331 and 1337(a).

25 9. Venue is proper in this Court pursuant to section 12 of the Clayton Act,
26 15 U.S.C. §22, because Abbott is an inhabitant of this District or is found or transacts business
27 there. Venue is also proper pursuant to 28 U.S.C. §1391.

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1 **TRADE AND COMMERCE**

2 10. The pharmaceutical products at issue in this case are sold in interstate
3 commerce, and the unlawful activities alleged in this Complaint have occurred in, and have had
4 a substantial effect upon, interstate commerce.

5 **FACTUAL BACKGROUND**

6 11. PIs are considered the most powerful treatment in the medical battle
7 against HIV and the disorders it causes, including acquired immune deficiency syndrome
8 (AIDS). These drugs work by blocking the action of protease, an enzyme needed for HIV to
9 reproduce and infect other cells.

10 12. There are several PIs currently on the market, including Norvir,
11 manufactured by Abbott and introduced in 1996, and Kaletra, also manufactured by Abbott and
12 introduced in 2000. Kaletra is a combination drug consisting of Norvir and another Abbott PI,
13 whose chemical or generic name is lopinavir. As explained below, while Norvir was
14 introduced as a stand-alone treatment, its principal use today is to boost the therapeutic effects
15 (and reduced the required dosage) of other PIs.

16 13. Abbott developed Norvir with the assistance of a National Institutes of
17 Health grant and spent only about \$15 million of its own funds on pre-approval clinical trials
18 for the drug. By the end of 2001, Norvir had generated cumulative sales for Abbott of more
19 than \$1 billion. Securities analysts have estimated that, even without the price increase that is
20 the subject of this Amended Complaint, Norvir would have generated more than \$2 billion for
21 Abbott over the next ten years.

22 14. After Norvir's release, it was discovered that, when used in small
23 quantities with another PI, Norvir would boost the anti-viral effects of the other PI. Not only
24 did a small dose of Norvir make other PIs more effective and decrease side effects associated
25 with high doses, but it also slowed down the rate at which HIV developed resistance to the
26 effects of PIs. Norvir is the only PI known to have such properties and, as a result, for such
27 "boosting" purposes, there is no substitute for Norvir. In addition to its direct therapeutic
28 benefits, a regimen consisting of a PI boosted by Norvir improves convenience for patients in

1 comparison to an unboosted regimen by reducing the required dosage of the PI and lessening
2 food restrictions, both important factors in ensuring adherence to HIV antiviral therapy.

3 15. Recent research has also shown significant benefits from the use of
4 boosted PI regimens, especially for patients who experience failure of treatment regimens
5 combining PIs with other anti-HIV drugs. Such treatment failures are marked by the
6 emergence of drug-resistant mutations that limit the benefits of other drugs in the future,
7 because of cross-resistance among HIV medications. When patients experience failure of
8 initial boosted PI regimens, there is no evidence of PI resistance and, moreover, there is less
9 resistance to other drugs in the regimen. Hence, by using Norvir as a booster, physicians can
10 maximize the treatment options remaining for the patients experiencing treatment failure.

11 16. As noted above, Abbott also markets Kaletra, which consists of Norvir
12 and another Abbott PI, lopinavir, combined in a single pill. Kaletra is lopinavir boosted by
13 Norvir. Although effective and widely used, Kaletra has significant side effects, including
14 hyperlipidemia, which renders patients more vulnerable to heart attacks and strokes.

15 17. Thus, in the “boosting” market, Norvir is the only product available,
16 while in the “boosted” market, Kaletra competes with other PIs, each of which is prescribed
17 and taken in conjunction with Norvir. This creates a situation in which the same firm
18 participates in two closely related markets, with the product sold in one of the two markets
19 being an input or component of the product sold in the other market. If such a firm lacks
20 competition in the market for sales of the input or component product, it may be able to use its
21 monopoly position in that market to disadvantage its competitors in the related market and
22 monopolize or attempt to monopolize the related market. That is exactly what Abbott has done
23 here.

24 **ABBOTT’S ANTICOMPETITIVE CONDUCT**

25 18. Prescriptions for Kaletra rose steadily from its introduction in September
26 2000 through mid-2003, at which point it enjoyed approximately a 75% share of the boosted PI
27 market. However, Kaletra’s dominance of the boosted market was about to be threatened.

28 19. In June 2003, Bristol-Myers Squibb introduced Reyataz, a PI designed to

1 be boosted by Norvir. In October 2003, GlaxoSmithKline introduced Lexiva, another PI
2 designed to be boosted by Norvir. Studies showed that, when boosted with Norvir, the new PIs
3 were as effective as Kaletra, and were more convenient. As a result, Kaletra's share of the
4 boosted market began to decline. The average daily dose of Norvir also fell. Before the release
5 of Reyataz, the most common boosting dose of Norvir ranged from 200 milligrams to 400
6 milligrams per day. However, clinical trials showed that a Norvir dose of only 100 milligrams
7 a day effectively boosted Reyataz.

8 20. Beginning in the second half of 2003, both Reyataz and Lexiva began to
9 make steady inroads into Kaletra's share of the boosted PI market.

10 21. Abbott was well aware of the competitive threat posed by Reyataz and
11 Lexiva and acted quickly to suppress it. On December 3, 2003, Abbott raised the wholesale
12 price of Norvir by approximately 400%, from \$205.74 to \$1,028.71 for a 120-count bottle of
13 100 mg capsules. However, Abbott did not raise the price of Kaletra, which incorporates
14 Norvir. In effect, Abbott raised the price of Norvir only when it is used to boost a non-Abbott
15 PI. By instituting this enormous price hike, Abbott drastically increased the cost of regimens
16 using Norvir to boost competing PIs. The annual cost of Norvir needed in such a regimen
17 increased by \$6,258 per year for PIs such as Lexiva requiring twice-daily dose of Norvir. For
18 Aptivus (tipranavir), a new PI marketed by Boehringer Ingelheim, the optimal Norvir booster
19 dose increased by more than \$12,000 per year.

20 22. Faced with the prospect of new competition to Kaletra, Abbott's boosted
21 PI, Abbott declined to engage in legal and procompetitive approaches to defending Kaletra's
22 market share (such as reducing Kaletra's price). Instead, its executives formulated an
23 anticompetitive scheme using Abbott's control of Norvir as leverage to maintain and/or
24 enhance Kaletra's dominant market position. Abbott's executives were well aware that Abbott
25 had encouraged the use of Norvir as a booster and had caused patients, physicians and
26 competitors to rely on the availability of Norvir. Abbott's executives realized that if Abbott
27 could make Norvir unavailable or less desirable when paired with its competitors' PIs—by
28 actually pulling it from the market (which it seriously considered) or by drastically raising its

1 price (which it did)—then its competitors’ products in the boosted market would cease to be a
2 significant competitive threat.

3 23. Abbott’s December 3, 2003 price increase was an attempt to leverage its
4 monopoly position in the boosting market in order to disadvantage competitors and maintain its
5 dominant position in the boosted market. The attempt succeeded.

6 24. Abbott’s leveraging scheme effectively halted the decline in market
7 share of Kaletra. By 2006, Kaletra’s share of the boosted PI market had risen to approximately
8 75%, the same share it held prior to the introduction of Reyataz. This change of course was
9 due entirely to the competitive disadvantage imposed on non-Abbott PIs by the December 2003
10 price increase.

11 **RELEVANT MARKETS**

12 25. There are two product markets relevant to Plaintiffs’ antitrust claims: the
13 boosting market, which consists of Norvir, and the boosted market, which consists of Kaletra
14 and a number of non-Abbott PIs, each of which is prescribed and used in conjunction with
15 Norvir. The relevant geographic market is the United States. With respect to both product
16 markets, a firm that was the only seller of such products in the United States would have the
17 ability to sell those products at a price substantially above marginal cost without losing
18 significant sales.

19 26. At all relevant times, Abbott has had a 100% share of the boosting
20 market and a dominant share of the boosted market. At all relevant times, Abbott possessed
21 monopoly power—the ability to raise price significantly above marginal cost without losing
22 significant sales—in both relevant markets.

23 27. There are barriers to entry in both the market for PI boosters and the
24 market for boosted PIs. The products in these markets require significant investments of time
25 and money to design, develop and distribute. In addition, both markets require government
26 approvals to enter and may be covered by patents or other forms of intellectual property. Thus,
27 existing and potential market entrants lack the ability to expand output quickly in the short run
28 in response to higher prices or reductions in output by the dominant firm.

1 28. The unlawful actions alleged above were taken for the purpose of
2 maintaining Abbott's dominant share of the boosted market.

3 **FIRST CAUSE OF ACTION**

4 **Monopolization (15 U.S.C. § 2)**

5 29. Plaintiffs incorporate by reference the allegations contained in
6 paragraphs 1 through 28 above.

7 30. At all relevant times, Abbott has had monopoly power in both the
8 boosting market and the boosted market.

9 31. Abbott has willfully maintained its monopoly power in the boosted
10 market through exclusionary and anticompetitive means. As described in more detail above,
11 Abbott raised the price of Norvir by approximately 400% in December 2003, and has
12 maintained that price to the present day, but only when Norvir is used to boost a non-Abbott PI.
13 Norvir is sold at a much lower price when used as one component of Abbott's own boosted PI,
14 Kaletra. By instituting such a price increase, Abbott has used its monopoly position in the
15 boosting market to gain a competitive advantage and disadvantage its competitors in the
16 boosted market. The purpose and effect of Abbott's conduct have been to suppress rather than
17 promote competition on the merits.

18 32. There is no procompetitive justification for Abbott's conduct.

19 33. Plaintiffs (or their assignors) have been injured in their business and
20 property by reason of Abbott's unlawful monopolization. Plaintiffs' injury consists of paying
21 higher prices to purchase Norvir and Kaletra than they would have paid absent Abbott's
22 conduct. This injury to Plaintiffs' business and property is injury of the type the antitrust laws
23 were designed to prevent and flows from that which makes Abbott's conduct unlawful.

24 34. Abbott's unlawful conduct threatens continuing loss and damage to
25 Plaintiffs if not enjoined by this Court.

26 **SECOND CAUSE OF ACTION**

27 **Attempt to Monopolize (15 U.S.C. § 2)**

28 35. Plaintiffs incorporate by reference the allegations contained in

1 paragraphs 1 through 28 above.

2 36. At all relevant times, Abbott has had monopoly power in the boosting
3 market and a dangerous probability of achieving monopoly power in the boosted market.

4 37. Abbott has attempted to monopolize the boosted market through
5 exclusionary and anticompetitive means. As described above, Abbott raised the price of Norvir
6 by 400% in December 2003, and has maintained that price to the present day, but only when
7 Norvir is used to boost a non-Abbott PI. Norvir is sold at a much lower price when used as one
8 component of Abbott's own boosted PI, Kaletra. By instituting such a price increase, Abbott
9 has used its monopoly position in the boosting market to gain a competitive advantage and
10 disadvantage its competitors in the boosted market. The purpose and effect of Abbott's
11 conduct have been to suppress rather than promote competition on the merits.

12 38. At all relevant times, Abbott has had the specific intent to monopolize
13 the boosted market.

14 39. There is no procompetitive justification for Abbott's conduct.

15 40. Plaintiffs (or their assignors) have been injured in their business and
16 property by reason of Abbott's unlawful attempted monopolization. Plaintiffs' injury consists
17 of paying higher prices to purchase Norvir and Kaletra than they would have paid absent
18 Abbott's conduct. This injury to Plaintiffs' business and property is injury of the type the
19 antitrust laws were designed to prevent and flows from that which makes Abbott's conduct
20 unlawful.

21 41. Abbott's unlawful conduct threatens continuing loss and damage to
22 Plaintiffs if not enjoined by this Court.

23 WHEREFORE, Plaintiffs pray for judgment against Defendants and for the
24 following relief:

25 A. A judgment for three times the damages sustained by Plaintiffs, as
26 determined by a jury;

27 B. A declaration that Abbott has violated the antitrust laws in the ways
28 described above;

1 C. Permanent injunctive relief which enjoins Abbott from continuing its
2 unlawful conduct, and requires Abbott to take affirmative steps to dissipate the anticompetitive
3 effects of its prior violations;

4 D. The costs of this suit, including a reasonable attorneys' fee; and

5 E. Such other and further relief as the Court deems just and proper.

6 **Jury Trial Demand**

7 Plaintiffs demand a trial by jury of all issues so triable.

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9 Dated: November 29, 2007

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